[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS

ACTION: Notice

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR Part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301-496-7057; fax: 301-402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: Technology descriptions follow.

Novel Radio-labeled Agents for Imaging Alzheimer's Disease-associated Amyloid

Description of Technology: This technology introduces novel radio-labeled agents for imaging amyloid deposits in the brains of Alzheimer's disease patients. These are small molecule, radio-ligand compounds that are analogs of benzo[d]thiazole. They are highly specific to amyloid, have low background noise, do not undergo rapid defluoridation and do not produce residual radioactivity in the brain. In addition, the compounds are stable and may be readily synthesized from commercially available starting materials. These compounds may be used in many noninvasive imaging techniques including: magnetic resonance spectroscopy (MRS) or imaging (MRI) or positron emission tomography (PET) or single-photon emission computed tomography (SPECT) to measure amyloid. Non-invasive detection of Alzheimer's disease-associated amyloid plaques in the brain would be valuable for early diagnosis, monitoring, and for clinical development of therapeutic drugs.

Potential Commercial Applications: Imaging agents for use in magnetic resonance spectroscopy (MRS), or imaging (MRI), positron emission tomography (PET) or single -photon emission computed tomography (SPECT).

Competitive Advantages: Highly specificity to amyloid, low background, do not undergo rapid defluoridation and do not produce residual radioactivity in the brain.

Development Stage: Early-stage

Inventors: Lisheng Cai and Victor W. Pike (NIMH)

Publications:

1. Cai L, et al. Synthesis and structure-affinity relationships of new 4-(6-iodo-H-imidazo[1,2-a]pyridin-2-yl)-N-dimethylbenzeneamine derivatives as ligands for human beta-amyloid plaques. J Med Chem. 2007 Sep 20;50(19):4746-58. [PMID 17722900]

2. Cai L, et al. Synthesis and evaluation of N-methyl and S-methyl 11C-labeled 6-methylthio-2-(4'-N,N-dimethylamino)phenylimidazo[1,2-a]pyridines as radioligands for imaging

beta-amyloid plaques in Alzheimer's disease. J Med Chem. 2008 Jan 10;51(1):148-58. [PMID 18078311]

Intellectual Property:

• HHS Reference No. E-225-2011/0 - US Provisional Application No. 61/535,569 filed 16 Sep 2011

• HHS Reference No. E-225-2011/1 - PCT Application No. PCT/US2012/055124 filed 13 Sep 2012, which published as WO 2013/0401830 on 21 Mar 2013; US Patent Application No. 14/345,004 filed 23 Apr 2014

Related Technology: HHS Reference No. E-156-2006/0 - US Patent No. 8,703,096 issued 22 Apr 2014; US Patent Application No. 14/223,782 filed 24 Mar 2014; Various international patents/applications issued/pending

Licensing Contact: Jennifer Wong; 301-435-4633; wongje@mail.nih.gov

Collaborative Research Opportunity: The National Institute of Mental Health (NIMH) is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize Beta-amyloid Imaging Agents. For collaboration opportunities, please contact Suzanne L. Winfield, Ph.D. at winfiels@intra.nimh.nih.gov or 301-402-4324.

Human Research Information System (HuRIS)

Summary: Researchers at the National Institute on Drug Abuse (NIDA) seek licensing or co-development of a Human Research Information System (HuRIS) software that automates all major functions of a clinical-research entity. The system is designed for commercial healthcare providers, community treatment centers, and clinical research facilities.

Description of Technology: The available system is the Human Research Information System (HuRIS), an integrated advanced clinical/research informatics series of systems—that is, an intelligent electronic environment for the collection, organization and retrieval of information

in clinical/scientific decision support—which enables data and resource sharing in real time among authorized users at our clinics. (Individual systems or subsystems may be licensable.) Users on both the clinical side (e.g. doctors writing medication orders or nurses recording participants' vital signs) and on the research side (e.g. researchers conducting data analysis or completing reporting requirements) have access to the information on demand. At the core of this informatics infrastructure reside the clinical charts and research records of participants compiled over the entire history of their study participation, and sometimes across multiple studies. The computerized recording of participants' information starts from the time of their initial consent for screening. Data collected by our intake personnel under a screening protocol become part of the participants' clinical research records. This recording continues as participants are admitted to a clinical trial and persists throughout their progress within the prescribed activities until they are discharged. The electronic recording of participants' activities enables the use of this information as a research resource to different groups at different locations, in current and future protocols, as permitted by human subjects' protection regulations. The HuRIS has a number of intelligent decision systems built-in for real-time or on-demand query as well as HL-7 communications with external laboratories for data exchange, and it seamlessly communicates with our Human Biospecimen Tracking System. User permissions to access various components of the system are centrally controlled and all access is logged.

Potential Commercial Applications:

- Hospital Information Management
- Clinical Research Information Management
- Pharmacy Management System
- Biospecimens Tracking System
- Laboratory Information Management
- Behavioral Modification/Addiction Treatment

Competitive Advantages:

• Mature solution developed with contributions by numerous physicians, scientists, and treatment professionals at all levels

• Low-cost mechanism

• Proven advantage in prior clinical studies

Development Stage:

• Ready for commercialization

• Prototype

• Clinical

Inventors: Massoud R. Vahabzadeh, Mustapha Mezghanni, Jia-Ling Lin, Michelle K. Leff (all of NIDA)

Publications:

1. Massoud Vahabzadeh, Jia-Ling Lin, Mustapha Mezghanni, Carlo Contoreggi, and Michelle Leff, "An EHR-Based Multi-Site Recruiting System for Clinical Trials," Proc. 20th IEEE International Symposium on Computer-Based Medical Systems, June 2007, pages 331-6.

2. Massoud Vahabzadeh, Jia-Ling Lin, Mustapha Mezghanni, David Epstein, and Kenzie Preston, "Automation in an Addiction Treatment Research Clinic: Computerized Contingency Management, Ecological Momentary Assessment, and a Protocol Workflow System," Drug and Alcohol Review, 28(1):3-11, January 2009.

Intellectual Property: HHS Reference No. E-266-2014/0 - Software. No patent protection is being sought.

Contact Information: Vio Conley, M.S.; NCI Technology Transfer Center; Phone: 240-276-5531; E-mail: conleyv@mail.nih.gov

Keywords: Software, Clinical Information System, Research Information System, Medical Decision Support System (DSS), Electronic Hospital Records (EHR), Physicians Order Entry (POE), Pharmacy Information System, Laboratory Information Management (LIM), Biospecimen Tracking System, Substance abuse, Drug addiction, Mental health, mPAL, HuRIS

Optimized Gene Therapy Vector for the Treatment of Glycogen Storage Disease Type Ia

Description of Technology: NIH researchers have developed an adeno-associated viral (AAV) vector for the treatment of glycogen storage disease type Ia (GSD-Ia). GSD-Ia is an inherited disorder of metabolism associated with life-threatening hypoglycemia, hepatic malignancy, and renal failure caused by the deficiency of glucose-6-phosphatase-alpha (G6Pase-alpha or G6PC). This new AAV vector that expresses human G6Pase-alpha directed by the tissue-specific human G6PC promoter/enhancer incorporates two improvements: 1) it expresses a variant of G6Pase-alpha with enhanced enzymatic activity; 2) it is codon optimized to achieve higher enzyme expression levels and enhanced enzymatic activity.

Current therapy, which primarily consists of dietary modification, fails to prevent long-term complications in many patients, including growth failure, gout, pulmonary hypertension, renal dysfunction, osteoporosis, and hepatocellular adenomas (HCA). Gene therapy-based techniques, which directly address the underlying genetic deficiency driving the disorder, offer the prospect of long-term remission in patients with GSD-Ia.

Potential Commercial Applications: Gene therapy vector for the treatment of GSD-Ia.

Competitive Advantages:

• Protein coding sequence modified for enhanced enzymatic activity.

• Codon optimized for increased enzyme expression in target organs.

Inventor: Janice J. Chou (NICHD)

Development Stage: In vivo data available (animal)

Publications:

1. Lee YM et al. Prevention of hepatocellular adenoma and correction of metabolic abnormalities in murine glycogen storage disease type Ia by gene therapy. Hepatology 2012 Nov;56(5):1719-29. [PMID 22422504]

2. Lee YM, et al. The upstream enhancer elements of the G6PC promoter are critical for optimal G6PC expression in murine glycogen storage disease type Ia. Mol Genet Metab. 2013 Nov;110(3):275-80. [PMID 23856420]

Intellectual Property: HHS Reference No. E-039-2015/0-US-01 - US Provisional Patent Application 62/096,400 filed December 23, 2014

Related Technologies: HHS Reference No. E-552-2013/0 - US Provisional Patent Application No. 61/908,861 filed November 26, 2013; PCT Application No. PCT/US2014/067415 filed November 25, 2014

Licensing Contact: Surekha Vathyam, Ph.D.; 301-435-4076; vathyams@mail.nih.gov

Collaborative Research Opportunity: The National Institute of Child Health and Human Development is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize gene therapy vectors for the treatment of glycogen storage disease type Ia. For collaboration opportunities, please contact Joseph M. Conrad, III, Ph.D., J.D. at jmconrad@mail.nih.gov.

Dated: September 25, 2015

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Richard U. Rodriguez, M.B.A.
Acting Director
Office of Technology Transfer
National Institutes of Health

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